The Office Action asserts that *Scheicher* discloses a drill head and bone drill "which could be used as a milling apparatus for preparing surfaces of two opposing vertebral bodies to accept a predetermined shape of an endoprosthesis". However, this conjecture does not amount to a *prima facie* showing of anticipation as required by § 102(b). That is, *Scheicher* explicitly discloses that the drill head and bone drill are used to drill into bone such as a jaw ridge 6 as shown in the Figures. The operation and configuration of the drill taught by *Scheicher* necessarily drills holes or cavities into a bone. To conjecture that such a drill could be used as a milling apparatus for preparing specifically shaped surfaces of opposing vertebral bodies is certainly not explicitly taught by *Scheicher* nor would it even be inherent since the explicit purpose for the drill taught by *Scheicher* is to create holes or cavities in a bone and not for use with opposing vertebrae. Indeed, if the cutters 5 of *Scheicher* were transversely inserted along their longitudinal axis between vertebral bodies, such a use would be far outside the usable function of the drill of *Scheicher* taught in this reference. Accordingly, *Scheicher* does not explicitly or inherently disclose the claimed form cutter having a profile capable of imparting a shape to the bone of opposing vertebral bodies as featured in independent Claims 1, 15 and 18.

Furthermore, since the Office Action references column 7 [sic], line 56, as teaching a profile of the form cutter approximately 9 mm in width, it appears that the conjecture made is that the cutters 5 of *Scheicher* would be capable of insertion between vertebral bodies along their longitudinal axis, as alluded to above. This being the case, only a portion of the cutters would be capable of contact with a vertebral body, which is in contradiction to the taught proper usage of Applicants' drill head. Specifically, the drill is shown to drill straight down into a bone such that all sides of the cutters 5 are touching bone as they drill in order to impart the correct shape in the bone. This proper operation of the *Scheicher* drill head and cutters 5 would not be possible if inserted longitudinally between two opposing vertebral bodies, which evinces that the rejection lacks merit and is merely conjecture contrary to the clear teachings of the reference. Accordingly, a *prima facie* case of anticipation, whether explicit or inherent, cannot be made based upon the *Scheicher* reference.

In addition, the Applicants note that in paragraph 3 of the present Office Action, it appears that the Examiner may be relying upon principles of inherency to teach the claimed feature of a form cutter capable of imparting shape to the bone of opposing vertebral bodies. However, the fact that a certain result or characteristic may occur or be present in the prior art[1] is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ 2d 1955, 1957 (Fed. Cir. 1993). Rather, in relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. (See M.P.E.P. § 2112). As explained above, imparting a shape to the bone of opposing vertebral bodies is not an inherent characteristic that necessarily flows from the teachings of *Scheicher*, which teach a bone drill for drilling holes in a bone. Accordingly, the Applicants respectfully submit that the apparent resort by the Examiner to the principles of inherency are misapplied in the present rejection.

Furthermore, with respect to Claims 14 and 17, in particular, the Office Action asserts that the profile of the cutters 5 is approximately 9 mm. In support, column 7, line 56, is referenced (the Applicants note that this reference appears to be a typographical error since column 17, line 56 includes teaching about specific distances between rotational axes 9 of the cutters 5). Although *Scheicher* teaches that the distances between the rotational axes 9 of the cutters 5 are within a range of 2.5 mm to 10 mm, these distances have no direct relationship to the profile of the cutters 5 in the drilling direction (e.g., parallel to distance B shown in Figure 1). Furthermore, Claim 20, requires that the profile of the rotary form cutter contained within the housing be not more than approximately 9 mm in height. *Scheicher* does not appear to disclose or suggest this feature since the profile of the housing including the drill head 4 along with the cutters 5 could not be 9 mm or less. Even assuming that the distance A shown in Figure 1 is the minimum 2.5 mm, the relative scale of the distance B plus the height of the drill head casing 11 would not be 9 mm or less.

---

[1] This is not to suggest or admit, however, that the result of the present invention (i.e., milling of opposing vertebral bodies) may occur in *Scheicher*, since it could not, as discussed previously.

The Office Action further asserts that the cutters 5 have a support shaft 8 that forms an angle approximately 96° to the drive means 11. However, the disclosure of *Scheicher* is devoid of any teaching that the angle between the support shaft 8 of the cutters 5 is anything but the 90° angle shown in all of its figures. Merely because this feature is claimed as "approximately 96°", this language does not provide license for the Examiner to conjecture that approximately 96° would be the same as a 90° right angle. Indeed, the specification clearly teaches that the angle between the support shaft of the form cutter and the drive shaft is approximately 96° to provide a designed orientation to the vertebral bone surface being milled. Thus, this angle is of particular significance to the particular application of the present invention. *Scheicher*, on the other hand, does not in any way teach or suggest milling vertebral bone surfaces nor that the angle between the support shafts 8 and the drive means could be anything but the 90° angle shown.

Claims 2-7, 13, 16, 19, 21, 23, and 24, are believed to be allowable at least by their dependency upon independent Claims 1, 15, and 18, respectively.

In light of the foregoing comments, the Applicants submit that a *prima facie* case of anticipation has not been properly established in the present Office Action and request withdrawal of the rejection under § 102(b) of Claims 1-7 and 13-24. Furthermore, the Applicants submit that these claims further are patentable under §103(a) since *Scheicher* does not even suggest the features of the present invention.

Claim Rejections - 35 U.S.C. § 103

Claims 8-12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over *Scheicher* in view of *Tschudin* (U.S. Patent No. 4,781,072). Without commenting on the merits of this rejection, the Applicants respectfully submit that these claims are at least allowable by virtue of their dependency upon independent Claim 1.

Conclusion

In light of the foregoing comments, the Applicants respectfully submit that the application is in condition for allowance. If there are any outstanding issues that may be resolved by an Examiner's Amendment or an interview, the Examiner is invited to telephone the undersigned attorney in order to expedite prosecution.

Respectfully submitted,

(Reg. No. 26,494)

Todd S. Parkhurst
HILL & SIMPSON
A Professional Corporation
85th Floor Sears Tower
Chicago, Illinois 60606
(312) 876-020
ATTORNEY FOR APPLICANTS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited in the United States Postal Service, First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on April 13, 2000.

Attorney for Applicants